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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/211,691	12/14/1998	MICHEL GILBERT	14137-129-10	9572

20350 7590 11/22/2004

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/211,691

Applicant(s)

GILBERT ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 October 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 37-48.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Manjunath N. Rao, Ph.D.  
Primary Examiner  
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***Advisory Action***

Claims 38-43 are now currently pending in this application.

Applicant's request for reconsideration filed on 10-29-04 has been considered and ENTERED. However, the rejection of claims 38-43 as obvious under 35 U.S.C. 103(a) is still maintained for the following reasons.

In response to the previous rejection of claims 38-43 as obvious under 35 U.S.C. 103(a), applicants continue to assert that the cited references alone or in combination fail to teach or suggest all the elements of the claimed invention. Furthermore, applicants have now invoked the doctrine of unexpected results that are not taught or suggested by the cited references.

Applicants now argue that the claimed fusion proteins are more soluble, more stable and are more efficient than unfused proteins and that the listed advantages are not shared with the teachings of cited references.

Examiner respectfully disagrees with such arguments and takes the position that such results are not unexpected after all. While Examiner agrees with the applicants that MPEP clearly states the evidence of unexpected results can be used to support a finding of unobviousness of the claims (MPEP 716.01), such evidence needs to be carefully evaluated. In the instant case applicants admit that Bulow et al. does teach or suggest the advantages of fusion proteins which includes changes, even though modest as it may be, in certain characteristics of the protein such as pH optima and stability. Therefore, such a teaching was already present in the art even though it was not for the particular enzyme. With such a teaching in hand it would have been obvious to those skilled in the art to make fusion proteins to explore and use those advantages. MPEP also states (716.02(b)) that evidence relied upon should establish "that the

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differences in results are in fact unexpected and unobvious and of both statistical and practical significance". *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter 1992). In the instant case, since it was already well known that characteristics of a protein can be changed by making it as a fusion protein, applicants have not clearly shown that the results in the claimed invention indeed had both statistical and practical significance. Applicants have clearly not shown as to what was the practical significance of their unexpected results, over and above that was already taught by Bulow et al. (in combination with other references).

Therefore, Examiner continues to maintain the above rejection.

#### ***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306/9307 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is fluid and cursive, with a large initial "M" and a stylized "R".

Manjunath N. Rao, Ph.D.  
Primary Examiner  
Art Unit 1652

November 18, 2004